Division of Medical Assistance	Clinical Coverage Policy No. 11H
Bone Morphogenic Protein-2	Original Date: January 1, 2005
	Revised Date: December 1, 2005

1.0 Definition of the Procedure

Bone morphogenic protein-2 (BMP-2) is a bioengineered osteoinductive protein that plays an important role in bone growth. Two products have currently received FDA approval and are implanted during spinal infusion surgery.

1. **InFuse Bone Graft/LT-Cage (Lumbar Tapered)**
   This device consists of three components split between two parts: a metallic tapered spinal fusion cage known as the (LT-cage lumbar tapered fusion device), and InFuse Bone Graft. InFuse Bone Graft is a bone graft substitute which consists of genetically engineered human protein (rrBMP-2) along with a carrier/scaffold for the protein (manufactured from bovine Type 1 (collagen) that is placed inside the fusion.
2. **OP-1 implant**
   This product treats long bone non-unions where autograft is not feasible and other treatments have failed. It is made of a manufactured human protein powder and bovine bone collagen that is mixed with a sterile saline solution to form a paste. The paste is then placed between the broken ends of the bone during surgery.

2.0 Eligible Recipients

2.1 General Provisions

Medicaid eligible individuals with a need for this specialized treatment confirmed by a licensed physician are eligible as long as they meet individual eligibility requirements. Medicaid recipients may have service restrictions due to their eligibility category, which would make them ineligible for this service.

2.2 Special Provisions

Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) is a federal Medicaid requirement that provides recipients under the age of 21 with medically necessary health care to correct or ameliorate a defect, physical or mental illness or a condition identified through a screening examination. While there is no requirement that the service, product or procedure be included in the State Medicaid Plan, it must be listed in the federal law at 42 U.S.C. § 1396d(a). Service limitations on scope, amount or frequency described in this coverage policy do not apply if the product, service or procedure is medically necessary.

The Division of Medical Assistance's policy instructions pertaining to EPSDT are available online at http://www.dhhs.state.nc.us/dma/prov.htm.

3.0 When the Procedure is Covered

The N.C. Medicaid program covers bone morphogenic protein allograft for patients who meet the following criteria:

1. Tapered lumbar fusion cages in single level anterior lumbar spine fusion
2. Long bone nonunion, when an autograft is not feasible and other treatments have failed

Each recipient's condition is evaluated on an individual basis. There may be other conditions that are indications for coverage.

4.0 When the Procedure is Not Covered

The N.C. Medicaid program does not cover bone morphogenic protein when one of the following conditions exists (not all inclusive):

1. Fusions of the thoracic or cervical spine
2. Multiple level lumbar fusions
3. Augmentation of bone auto grafting
4. Craniofacial surgery and fracture nonunions of other sites
5. Restorative dental surgery
6. History of or active substance abuse - must have documentation of substance abuse program completion plus six months of negative sequential random drug screens.

   Note: To satisfy the requirement for sequential testing as designated in this policy, the Division of Medical Assistance (DMA) must receive a series of test (alcohol and drug) results spanning a minimum six-month period, allowing no fewer than a three-week interval and no more than six-week interval between each test during the given time period. A complete clinical packet for prior approval must include at least one documented test performed within one month of the date of request to be considered.
7. Psychosocial history that would limit the ability to comply with medical care pre- and post-transplant.
8. Current patient and/or caretaker non-compliance that would make compliance with a disciplined medical regime improbable.

Each recipient's condition is evaluated on an individual basis. There may be other conditions that are indications for non-coverage.

5.0 Requirements for and Limitations on Coverage

All applicable N.C. Medicaid policies and procedures must be followed in addition to the ones listed in this procedure.

All procedures must be prior approved by DMA.

6.0 Providers Eligible to Bill for the Procedure

Physicians enrolled in the N.C. Medicaid program who perform this procedure may bill for this service.

7.0 Additional Requirements

FDA approved procedures, products, and devices for implantation must be utilized.

Implants, products, and devices must be used in accordance with all FDA requirements current at the time of surgery.

A statement signed by the surgeon certifying that all FDA requirements for the implants, products, and devices must be retained in the recipient's medical record and made available for review upon request.

8.0 Policy Implementation/Revision Information

Original Effective Date: January 1, 1994

Revision Information:

Date	Section Revised	Change
7/1/05	Entire Policy	Policy was updated to include coverage criteria effective with approved date of State Plan amendment 4/1/05.
9/1/05	Section 2.2	The special provision related to EPSDT was revised.
12/1/05	Section 2.2	The web address for DMA's EDPST policy instructions was added to this section.

Attachment A
Claims Related Information

Reimbursement requires compliance with all Medicaid guidelines including obtaining appropriate referrals for recipients enrolled in the Medicaid Managed Care programs.

A. Claim Type

1. Providers bill professional services on the CMS-1500 claim form.
2. Hospitals bill for services on the UB-92 claim form.

B. **Diagnosis Codes**

Providers must bill the ICD-9-CM diagnosis code to the highest level of specificity that supports medical necessity.

C. Procedure Codes

Codes that are covered include: 22851

D. Providers must bill their usual and customary charges.